<u>S/N 09/825,786</u> <u>PATENT</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gerald W. Mills et al. Examiner: William Jung

 Serial No.:
 09/825,786
 Group Art Unit: 3737

 Filed:
 April 4, 2001
 Docket No.: 723.035US1

Title: ROBOTIC TRAJECTORY GUIDE

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

This responds to the Office Action mailed on November 16, 2005. Please amend the above-identified patent application as follows.

IN THE CLAIMS

Please amend the claims as follows:

Claims 1-9 (Canceled)

10. (Currently Amended) An alignment system for an imaging device comprising: an alignment device comprising:

a base, the base having an affixation device to mount on a patient surface; an insertion guide, having an opening therein and an insertion axis through the opening; an adjustable joint attached to a distal end of the insertion guide, and coupled to the base;

[[a]] an MR compatible local adjustment device attached to the adjustable joint; an actuator <u>detachably</u> coupled to the local adjustment device, wherein the actuator is spaced apart from the local adjustment device to enable location of the actuator outside an imaging region of the imaging device while the local adjustment device is within the imaging region of the imaging device;

a control module in remote communication with the actuator and in communication with the imaging device, the control module aligning the insertion axis with the target location.

- 11. (Previously Presented) The alignment system of claim 10, wherein the control module includes a microcomputer.
- 12. (Original) The alignment system of claim 10, wherein the imaging device includes a magnetic resonance imaging (MRI) device.
- 13. (Original) The alignment system of claim 10, further including a first reference device coupled to the insertion guide, the first reference device being capable of locating the insertion axis in three dimensional space relative to a patient.

- 14. (Previously Presented) The alignment system of claim 13, further including a second reference device coupled to a patient reference frame, the second reference device being capable of locating the patient relative to the first reference device.
- 15. (Original) The alignment system of claim 13, wherein the first reference device includes a conducting coil capable of locating the insertion axis in three dimensional space relative to the patient.
- 16. (Original) The alignment system of claim 13, wherein the first reference device includes a number of LED devices capable of locating the insertion axis in three dimensional space relative to the patient.
- 17. (Original) The alignment system of claim 13, wherein the first reference device includes a number of infra red (IR) reflecting devices capable of locating the insertion axis in three dimensional space relative to the patient.
- 18. (Original) The alignment system of claim 13, wherein the first reference device includes a potentiometer capable of locating a primary medical device along the insertion axis.
- 19. (Original) The alignment system of claim 13, wherein the alignment system is a closed loop system.
- 20. (Currently Amended) A method of aligning a medical device comprising: coupling a base directly to a patient surface;

attaching an insertion guide to the base using an adjustable joint, the insertion guide having an insertion axis, and the adjustable joint having a range of motion;

attaching a local adjustment device to the adjustable joint;

coupling an actuator to the local adjustment device, wherein coupling the actuator to the local adjustment device includes remotely coupling the actuator to the local adjustment device; and

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remotely actuating the actuator to adjust alignment of the insertion axis within the range

of motion[[.]]; and

detaching the actuator from the local adjustment device upon completion of a procedure.

21. (Previously Presented) The method of claim 20, wherein coupling a base includes

attaching a base directly to the skull of a patient.

22. (Canceled)

23. (Original) The method of claim 20, wherein actuating the actuator includes engaging a

rotary motor, the rotary motor being coupled to the local adjustment device by a rotating cable

drive.

(Original) The method of claim 23, further including coupling the actuator to a remote 24.

control module, the remote control module being capable of adjusting the insertion axis by

remotely actuating the actuator.

25. (Original) The method of claim 24, further including:

imaging a patient with a tissue imaging device;

inputting a target location to the control module; and

computing an adjustment with the control module and aligning the insertion axis with the target

location through actuation of the actuator.

26. (Original) The method of claim 25, wherein computing an adjustment with the control

module and aligning the insertion axis includes computing an adjustment with the control

module and aligning the insertion axis using a closed loop system.

Claims 27-28 (Canceled)

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29. (Previously Presented) The alignment system of claim 10, wherein the adjustable joint includes a ball and socket joint.

- 30. (Previously Presented) The alignment system of claim 10, wherein the local adjustment device includes a linear slide coupled to the insertion guide.
- 31. (Previously Presented) The alignment system of claim 30, wherein the linear slide includes a threaded adjuster coupled to a collar, the collar being coupled to the insertion guide.
- 32. (Previously Presented) The alignment system of claim 31, wherein the collar includes a ball and socket joint coupled to the insertion guide.

REMARKS

This responds to the Office Action mailed on November 16, 2005, and the references cited therewith.

Claims 10 and 20 are amended, no claims are canceled, and no claims are added; as a result, claims 10-21, 23-26, and 29-32 remain pending in this application.

§103 Rejection of the Claims

Claims 10-17, 20, 21, and 29-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Franck et al (U.S.6,529,765) in view of Truwit (U.S. 6,206,890). Applicant respectfully traverses the rejection for at least the following reasons.

The rejection states that Franck discloses a local adjustment device and an actuator coupled to the local adjustment device. The rejection admits that Franck does not disclose a remote actuator spaced apart from the local adjustment device to locate the actuator outside an imaging region of the imaging device while the local adjustment is within the imaging region of the imaging device. The rejection states that Truwit shows in Figures 30-32 a mechanical remote actuation and control device 3000.

Truwit appears to show a "remote actuation and control device 3000" (column 14, lines 26-27). However, Applicant is unable to find in Truwit an actuator *detachably* coupled to the local adjustment device, wherein the actuator is spaced apart from the local adjustment device to enable location of the actuator outside an imaging region of the imaging device while the local adjustment device is within the imaging region of the imaging device. Embodiments shown in Figures 30-32 of Truwit do not appear to be detachable.

In contrast, claim 10 as amended includes an actuator detachably coupled to the local adjustment device, wherein the actuator is spaced apart from the local adjustment device to enable location of the actuator outside an imaging region of the imaging device while the local adjustment device is within the imaging region of the imaging device. Further in contrast, claim 20 as amended includes detaching the actuator from the local adjustment device upon completion of a procedure. Support for the amendments can be found in the specification in general, and at least on page 10, line 26 to page 11 line 7. Regarding detachable actuators, this section states that a more expensive actuator "can be reused, potentially without intensive sterilization, and the

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trajectory device can be more easily sterilized, or alternatively, disposed of after each procedure."

Further, claim 15 recites a first reference device including a conducting coil capable of locating the insertion axis in three dimensional space relative to the patient. Applicant is unable to find such a conducting coil in Franck.

Because the cited references, either alone or in combination, do not show every element of Applicant's independent claims, a 35 USC § 103(a) rejection is not supported by the references. Reconsideration and withdrawal of the rejection are respectfully requested with respect to Applicant's independent claims 10 and 20. Additionally, reconsideration and withdrawal of the rejection are respectfully requested with respect to the remaining claims that depend therefrom as depending on allowable base claims.

Claims 18, 19, and 23-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Franck et al (U.S. 6,529,765) in view of Truwit (U.S. 6,206,890), and further in view of Lee et al (U.S. 3,893,449). Applicant respectfully submits that the additional reference of Lee fails to cure the rejection based on Franck and Truwit for at least the reasons outlined above.

Because the cited references, either alone or in combination, do not show every element of Applicant's independent claims, a 35 USC § 103(a) rejection is not supported by the references. Reconsideration and withdrawal of the rejection are respectfully requested with respect to claims 18, 19, and 23-26.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6944 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

GERALD W. MILLS ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 373-6944

Date 2 -16-06

David C. Peterson

Reg. No. 47,857

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this <u>correspondence</u> is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16th day of February, 2006.

PATRICIA A. HULTMAN

Name

Signature